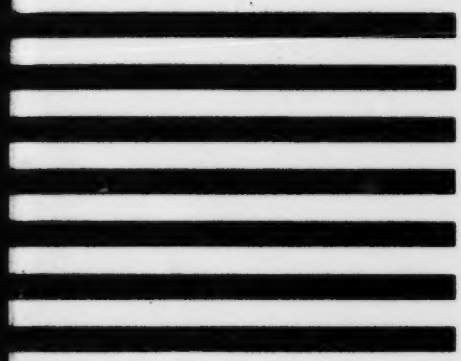

STORAGE AND UTILIZATION OF HUMAN SPERM

Report of the Advisory Committee to the Minister of National Health and Welfare

REPORT OF THE ADVISORY COMMITTEE ON THE STORAGE AND UTILIZATION OF HUMAN SPERM

TO

THE MINISTER OF NATIONAL HEALTH AND WELFARE

Également disponible en français sous le titre
"STOCKAGE ET UTILISATION DU SPERME HUMAN".

THE UNIVERSITY OF BRITISH COLUMBIA

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April 22, 1981

The Honourable Madame Monique Bégin
Minister of National Health and Welfare
Government of Canada
Ottawa

My Dear Madame Minister:

Re: Report of the Advisory Committee on the Storage and Utilization of Human Sperm

On April 7, 1977, the Honourable Marc Lalonde, at that time Minister of National Health and Welfare, commissioned our Committee for the purpose of providing advice on questions relating to sperm banks, and more generally to many aspects of the storage and utilization of human sperm. The terms of reference are attached (Appendix I).

We are grateful that Dr. Philip Banister was appointed as a staff member from your Ministry. We also obtained authorization to add Dr. David Roy as a committee member at a time when Dr. André Gombay was overseas on sabbatical, and we required expertise in bioethics.

As you know, the funding of this committee was discontinued at a time when drastic reductions were ordered throughout the Ministry, and much of our work was still to be done. At that time we were instructed to write a report on the material already available and we were financed to hold a final meeting.

While we consider the unfinished portion of our task quite important, we are satisfied that the recommendations and their basis will accomplish the main purpose for which our Committee had been commissioned.

In submitting this report, we emphasize our recommendation that the need for provincial legislation be presented in the strongest possible terms to the ten attorneys-general, and that public awareness of its content be encouraged widely.

...2

With our gratitude for the opportunity to serve,

Respectfully yours

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FOREWORD

At the Annual Conference of Provincial Ministers of Health in the autumn of 1974, concern was expressed about the potential hazards of commercial exploitation of the technique of preserving human sperm by freezing. Accordingly, the following recommendation was forwarded to the Minister of Health and Welfare for comments by the chairman of the group:

"Ministers of Health to request the Federal Government to prohibit the storage of human sperm on a commercial basis until further evaluation has taken place. Research and control studies to be carried out."

The Minister responded by suggesting that in view of the wide range of issues raised by the storage and use of stored sperm, he would consider establishing a committee to advise him on possible courses of action. Accordingly, an advisory committee was established on the Storage and Utilization of Human Sperm. It was constituted of members with a broad range of knowledge and experience in fields of Ethics, Biology, Law, Medicine, Philosophy and Religion.

The terms of reference (Appendix I) were provisionally accepted at an initial meeting held in September 1977.

In 1978 there was an unexpected rather significant reduction in funds available to the department which led to the work of the committee being terminated somewhat sooner than was originally intended.

Notwithstanding the above mentioned difficulties, this report makes a contribution to the delineation and understanding of some of the most important issues associated with artificial insemination, with particular reference to the use of sperm banks in Canada.

We would like to thank the Chairman, Dr. Sydney Segal, and the members of the Committee for their work and their determination to ensure that this report was completed.

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ACKNOWLEDGEMENTS

The Committee wishes to thank Dr. Marc S. Frankel, Wayne State University, Detroit Michigan whose assistance was sought because of his pioneering publication on the public policy aspects of sperm banks, and Dr. John C. Petricciani, Bureau of Biologics, National Institute of Health, Bethesda, Md., who responded on several occasions to questions about progress on subjects bearing upon regulatory policies for frozen sperm in the U.S. and who provided pre-publication workshop information on viral and toxic factors affecting spermatogenesis, as well as preliminary drafts of standards for human tissue banking, including sperm collection and storage.

Our consultants Dr. F. Clarke Fraser of Montreal and Dr. James R. Miller of Vancouver require special thanks for their repeated and updated guidance on the human genetic aspects of AID.

The Chairman acknowledges the dedication and patience of all of the Committee members, and recognizes the work of a final editorial subcommittee consisting of Drs. John Collins, Andre Gombay and Philip Banister. Dr. Banister, the Ministry's representative during the whole of the project, gave us the most generous support and his contributions were critically important in the completion of this report. Nor could the report have been completed without the able administrative and secretarial assistance of Monique Amyot and LouAnne Rosette.

INTRODUCTION

In 1977, the Minister of National Health and Welfare commissioned a committee to advise the government on artificial insemination (AI), with reference to the use of stored sperm. The committee was instructed to give special attention to the advisability of permitting commercial sperm banks to operate in this country.

It was anticipated that the practice of artificial insemination would continue to increase as one of the solutions for infertility, the choice being made because of the reduced availability of infants for adoption, and because of the desire of a woman to bear her own child. In 1974, the Royal Commission on Family and Children's Law in British Columbia recommended the enactment of provincial legislation concerning AI and stated that there should be a federal responsibility for the surveillance of sperm banks and for the quality of their services. This recommendation was supported by the provincial Deputy Minister of Health.

In order to address the various assignments included in its terms of reference, the committee examined the processes involved in AI. It concluded that the storage and use of frozen sperm could not be assessed without reference to the entire process of artificial insemination, with either fresh or frozen sperm. While it was not possible in the time available to consider all aspects of this broad subject, the committee identified three types of problems:

1. Problems concerning the law and the need for new legislation;

2. Problems concerning standards for the acquisition, preservation and utilization of sperm;

3. Ethical and social problems.

An overview. About one in ten Canadian couples is infertile. That is: pregnancy is desired and conception does not occur within one year. In more than one third of the infertile couples the delay is due to a partial reduction in the number or motility of the spermatozoa. Some husbands, however, have no sperm and while this condition does not affect potency or maleness, fertilization is impossible. Many couples who cannot otherwise expect a pregnancy now choose to conceive by the artificial insemination of donor sperm (AID).

More than 1,500 births have followed treatment of women by artificial insemination in Canada. Demand for the service is growing and there are now some eighteen clinics providing counselling or treatment. All of these clinics are in health science centres. No programme for the provision of AI existing outside a health science centre has come to our attention. Eleven of the eighteen centres have returned questionnaires, from which come our figures for their activity in 1979 (see Appendix II).

About ninety couples per month are referred to these centres, an increase from a few dozen per year in 1970, and about seventy in 1977. In eight of the eleven centres, fresh semen samples are used, while in three clinics donor sperm is frozen and kept in liquid nitrogen before being thawed for insemination. After the initial visit and the investigation that may be required, the insemination procedures require two

or more clinic visits each month. When pregnancy occurs, it usually does so after an average of six to seven inseminations, and this combined with the failures, explains why more than 500 inseminations are actually done each month in the Canadian clinics.

The number of donors in each clinic averages 34 and ranges from 7 to 120, and each donor provides about ten specimens per year. Among recipients, the average pregnancy rate is 59% and the doctors contacted claim that 1,519 babies have been born to couples who have received AID. There were eight babies with congenital defects, fewer than might have been expected in the same number of births in the general population. In the opinion of doctors who are familiar with the couples, emotional reactions that might harm the new family are also rare. The experience in Canada indicates that AID may give happiness to infertile couples with no more and possibly less risk than natural conception entails.

The Committee is of the opinion that AID is a socially acceptable and beneficial medical procedure. Nevertheless there is concern that as the demand increases, the beneficial results may be compromised unless care is taken to protect the couples and their hoped for children. The Committee urges acceptance of three recommendations that are fundamental to the protection of children who may be born as a result of artificial insemination of donor sperm. The committee recommends that:

1. there be provincial legislation to ensure that a child born by AID is recognized as a legitimate child of the mother and her consenting husband;

2. Federal regulations governing standards for the acquisition, preservation and importation of human sperm be established;

3. AID be available only where guidelines are met to safeguard the donor, the recipient and the progeny.

The recommendations are required because AID children are not clearly legitimate, because there are conflicting views on the standards to be adopted in the collection and utilization of sperm, and because there is no apparent agreement on the procedures required in clinics where AID is offered. The issues leading to the above recommendations are discussed in chapters I, II and III, and supplementary recommendations appear in the text.

In its consideration of the history and practice of AID in Canada the committee has recognized a range of ethical issues that contribute to the recommendations. It is as important to identify these issues as it is difficult to devise specific recommendations relating to them. Some of the more important ethical issues are defined in Chapter IV, (AID - An Overview of the Ethical Issues).

The committee accepts that while AID is a benefit conferred by the progress of medical science, the bearing of a child by AID is neither a right which should be claimed by anyone nor an obligation which should be imposed upon anyone. The recommendations of the committee come from discussions in which AID was considered in the context of the family, a context where the interests of one individual are modified by the interests of other family members. These considerations are dealt with in Chapter V (The Effects of AID on the Family).

Recommendations

1. There should be provincial legislation to ensure that a child born by AID is recognized as a legitimate child of the mother and her consenting husband.

   .1 Legislation should be drafted (by the Uniformity Commission of Canada) extending the definition of legitimacy to include children born through AID to which the husband of the mother has consented in writing (p.1).

   .2 The federal government should ensure that in all relevant federal legislation the definitions of "child" specifically include a child born through AID (where there is written consent of the mother's husband) (p.2).

   .3 Where necessary, amendments to provincial statutes should be made to require physicians at the birth of a child conceived through AID (where there was written consent of the mother's husband) to enter the name of the mother's husband as the name of the father (p.2).

2. Federal regulations governing standards for the acquisition, preservation and importation of human sperm should be established.

   .1 Standards for donated sperm should ensure in so far as is possible that the semen is not infectious, that the donor does not have a

transmissible disease, that the specimen has been collected properly and that storage conditions will not unnecessarily impair the quality of the specimen (p.5).

.2 The minimum standard to reduce the risk of genetic disease should be the completion of a detailed genetic inquiry (p.7).

.3 Minimum standards for number, motility and morphology of sperm in a specimen to be used for artifical insemination should be established (p. 11).

.4 Donor selection procedures should ensure that a limit to the number of pregnancies from any one donor may be set (p. 12).

.5 Until regulations establishing federal standards of quality are in effect for Canada, the importation of sperm from commercial human sperm banks should be prohibited; and no new human sperm bank should be allowed to operate outside the jurisdiction of a university or other publicly owned agency (p. 14).

In addition, it is recommended that long term follow-up studies should be carried out to provide an improved basis for future guidelines in the selection of potential donors for artificial insemination (p. 12).

3. AID should be available only where guidelines are met to safeguard the donor, recipient and progeny.

.1 Records should be maintained which collect all relevant and available information on the donor. A separate record should document the history and the physical, laboratory and follow-up data on the couple and the progeny (p.23).

.2 Provincial legislation should be passed to protect the donor from unfounded or frivolous legal action. When protective legislation exists, the committee recommends that links be kept between the records of the donor and those of the recipient (p. 24).

.3 Counselling for couples considering AID should include discussion of a wide range of clinical, ethical, legal and family issues (p. 25).

.4 Clinics offering AID should have for the donor and the recipient couple, clearly written consent forms using ordinary language which disclose the risks and responsibilities involved in the procedures which each of them is considering (p. 26).

.5 Routine pooling or mixing of sperm from different donors for artificial insemination should be avoided (p.29).

.6 In view of the legal risks to donors and physicians, the Minister of National Health and Welfare should bring this matter to the attention of the Provincial Ministers and encourage them promptly to enact remedial legislation (p.31).

CHAPTER I

LEGISLATION TO ENSURE LEGITIMACY FOR THE PROGENY OF AID

Effectively a child has few rights, legal or otherwise, except for those rights or privileges granted by an adult who is under a legal or moral duty to do so. Usually the only right the child has is the right to maintenance and support, as this can be legally enforced. Latterly, the Courts have also recognized, in cases of separation and divorce, that a child has a right of access to both parents, although in practice the enforcement of this right depends on their wishes and attitudes.

In the past, even the right to maintenance by the father was denied to a child who was illegitimate, i.e. born out of wedlock as a result of fornication or adultery. As society's view of the turpitude of these acts changed, so did the law. The legal concept of legitimacy was enlarged twice: firstly to include the child born from fornication where the parents subsequently marry; secondly, to include the child of an adulterous relation where the parents subsequently marry. These legal developments were resented by those who felt that this encouraged fornication and adultery, but they seemed acceptable overall since the parents, whose acts legitimized the child's status, were the child's biological parents; hence blood descent was ensured.

We hold that the concept of legitimacy should be further expanded to include the child born as a result of AID, where the husband and wife have consented in writing to the procedure. To suggest that the law should make a

distinction between a child born to loving and caring parents by means of natural insemination, and a child born to the same parents by means of artificial insemination, is wrong. If parents wish to have a child by AID they must surely be prepared to accept that child as a full member of the family unit and to provide for his or her needs and protection. Anything that society can do by legislation or otherwise to strengthen that family unit and those ties of love and responsibility, is of greater importance than defending the concept of hereditary succession.

At common law there is a presumption that a child born during the marriage is legitimate, and, unless this presumption is rebutted, the child's legal status is that of a child of the mother's husband. At present proof of AID could be such a rebuttal.

The Vital Statistics Act of Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, P.E.I. and Saskatchewan specifically require a married woman's child to be registered as the husband's child, showing his surname and his particulars. (The only exception permitted is where the mother and her husband were living separately at the time of the conception and the husband is not the biological father of the child). Under the Quebec Civil Code it is also proper to register the child as the husband's legitimate child.

A false entry of birth is an offence under Section 335 1(b) of the Canadian Criminal Code which reads as follows:

> "Everyone who unlawfully... inserts or causes to be inserted in a register or copy

referred to in paragraph (a) an entry that he knows is false, of any matter relating to a birth..., is guilty of an indictable offence and is liable to imprisonment for 5 years".

In other jurisdictions, this situation at present may cause a physician who carries out the insemination to prefer that another physician, with no knowledge of the AID, supervise the prenatal care and delivery. The possible connection between AID and the birth of an abnormal child then may be missed unless the first physician can arrange a follow up.

The Committee recognizes that a child's development depends upon social, psychological and other factors that go beyond legitimacy (some of these will be discussed in later sections). However, with respect to legitimacy, we recommend that:

1. There should be provincial legislation to ensure that a child born by AID is recognized as a legitimate child of the mother and her consenting husband.

   .1 Legislation should be drafted (by the Uniformity Commission of Canada) extending the definition of legitimacy to include children born through AID to which the husband of the mother has consented in writing.

   .2 The federal government should ensure that in all relevant federal legislation the definitions of "child" specifically include a child born through

AID (where there is written consent of the mother's husband).

.3 Where necessary, amendments to provincial statutes should be made to require physicians at the birth of a child conceived through AID (where there was written consent of the mother's husband) to enter the name of the mother's husband as the name of the father.

CHAPTER II

STANDARDS FOR THE ACQUISITION, PRESERVATION AND IMPORTATION OF SPERM

Standards must govern the quality of the donated sperm to ensure that it is not infectious, that the donor does not have a transmissible disease, and that the specimen has been collected properly. Such standards exist for other donated biological products, such as blood derivatives. In addition, standards for donated sperm are required to reduce the risks of genetic disease and the fear of the risks that might result from the presence in a community of multiple progeny from one parent.

There is controversy over the extent of these risks, hence a division of views over what standards are required. The committee has considered the views of geneticists, lawyers and physicians, and paid attention to the ethical dimension of the issue. In this chapter it proposes standards which seem appropriate at this time in Canada.

1. EVALUATION AND SELECTION OF DONORS

In this section we consider first the recruitment, interview, psychological evaluation, genetic screening and physical examination of donors; we then consider the methods of collection of the semen, semen characteristics, non-genetic factors affecting sperm, and number of donations.

Donor Recruitment Ideally a donor should be healthy, free of known hazardous genetic, medical or mental defects, without transmissible infections, and should have been the

father of at least one normal child. In many centres, it has become common for medical students to make up the majority of the donor pool. While this is convenient, and the continuous turnover of students in medical schools limits the number of pregnancies one donor is likely to produce, it is not necessarily desirable. Arguments may be put forward in favour of recruiting donors from more diverse backgrounds.

Donor Screening There should be at least one private interview of the prospective donor, covering such issues as motivation to donate sperm, the ethical and legal status of the AID program, record keeping, donor liability and technique of sperm acquisition. The prospective donor should be told that he will be informed about any congenital defect or genetic disease that might occur in a child born after AID using his sperm, where it is possible to establish that a single donor specimen resulted in the pregnancy.

Psychological Evaluation Ideally it is desirable to have a complete psychological evaluation of the donor, and of the donor's wife in the case of a married individual. In practice it has been found that the screening process described above and the inevitable delays involved in accepting donors provide considerable insight into the motivation of the prospective donor. It is not established whether or not comprehensive psychological evaluation could provide clear additional information about the possible effects of artificial insemination on the donor and/or his wife. While long follow up of donors and their families has not been routinely carried out, no unexpected emotional reaction to sperm donation has come to the attention of doctors and nurses in Canadian clinics.

Genetic Screening of Donors. Only a small number of prospective donors would have to be rejected on the basis of the possible transmission of an inheritable disease. Screening for such risks requires a physical examination of the potential donor, a personal history and a family history. Consultation with a medical geneticist may be useful in certain cases.

Genetic Criteria

1. The donor should be healthy. In particular he should not have, or have had:

   1.1 Any non-trivial malformation such as: cleft lip, cleft palate, meningomyelocele, congenital heart defect, congenital hip dislocation, congenital club foot, hypospadias.

   1.2 Any familial disease with a major genetic component in the etiology such as: asthma, diabetes mellitus, psychosis, epileptic disorder, hypertension, rheumatoid arthritis, severe refractive disorder.

   1.3 Any non-trivial Mendelian disorder such as: albinism, hemophilia, hemoglobin disorder, neurofibromatosis, tuberous sclerosis, hereditary hypercholesterolemia.

2. The donor should not be heterozygous for any recessively inherited gene known to be prevalent in the donor's racial group and for which heterozygosity can be detected such as: thalassemia and G6PD deficiency in Mediterranean races, sickle cell disease in blacks, Tay Sachs disease in Ashkenazi Jews and French Canadians.

3. The donor's first degree relatives (parents, sibs, children) should be free of:

3.1 The conditions referred to in 1.1.

3.2 Major psychoses, epileptic disorders, juvenile diabetes mellitus, early onset coronary disease (hereditary hypercholesterolemia).

3.3 Non-trivial disorders showing Mendelian inheritance in the following categories:

3.3.1 Autosomal dominant or X-linked inheritance with age of onset distribution that extends beyond the donor's age, such as Huntington disease, Landouzy-Dejerine muscular dystrophy, retinitis pigmentosa.

3.3.2 Autosomal dominant inheritance with reduced penetrance, such as: Marfan syndrome, retino-blastoma, Alport disease.

3.3.3 Autosomal recessive inheritance with a high frequency in the population such as: cystic fibrosis of the pancreas in Caucasians.

3.3.4 A chromosomal rearrangement or unbalance if other than a proven trisomy, unless the donor is found to have a normal karyotype.

Physical Examination. A thorough physical examination must be performed on the donor with emphasis on the detection of hypertension, diabetes, genetic defects or evidence of infection. In addition, laboratory tests should be carried out to establish blood levels of, for example, glucose, uric acid and cholesterol and to detect syphilis or evidence of viral infections associated with hepatitis. Urinalysis and culture of urine and semen are also required. (See below).

Collection of Semen Specimens for Insemination. A donor should be notified in sufficient time to allow for a minimum of 48 hours abstention from sexual activity before

the specimen is produced. At the time of the donation, the donor should be free of known venereal disease or prostatic infection.

Specimens for frozen storage should have cultures carried out. However, culture results of fresh specimens are not available until 24 to 48 hours after the insemination. Microscopic examination of fresh specimens at the time of insemination usually will identify significant bacterial infection. So, while cultures may be desirable, it is more practical and economical to perform a careful microscopic examination of the specimen immediately before the insemination.

A specimen is produced by masturbation and collected into a disposable inert wide-mouthed container with a conical bottom. The container label should contain the identification code of the donor and the date and time of ejaculation. The donor's name should not appear on the specimen container.

Since the fertilization rate of sperm is reduced after ninety minutes, the time from ejaculation until the specimen is available for examination should not exceed 30 minutes. The specimen should not be subjected to temperatures above 38° or below 20° Celsius. Room temperature is acceptable for short-term transportation. The specimen should be used for insemination or it should be frozen within 60 minutes of ejaculation.

Semen Analysis A thorough semen analysis must be carried out in a competent laboratory, usually in an academic or hospital centre. While considerable knowledge may be

obtained from a single specimen, more useful information will be found by having two or three collections performed over a period of four to six days. This would allow for more accurate confirmation of the number, motility and morphology of sperm, and would reveal any decline in sperm count after multiple ejaculations. While it is recognized that conception can occur with low sperm-counts, it is less likely; and we therefore recommend that minimum acceptable standards for number, motility and morphology of sperm should be established. Due to the high motility loss resulting from freezing, the need then for an adequate number of sperm in each ejaculate is even more critical. Minimum acceptable standards in some centres are: a total count of 60 million sperm per ml; normal morphology in excess of 60% of sperm; and normal motility at two hours in more than 60% of sperm.

Non-Genetic Factors affecting Sperm It is customary to screen any potential donor in order to reduce the chance of direct transmission of disease to the recipient. Chlamydia and Candida must be tested for, in addition to the standard tests for syphilitic or gonococcal infection in the donor. Recently, hepatitis has been found transmissible in seminal fluid. When stored sperm is used, each specimen can be examined prior to use. However, with fresh sperm, a donor found free of venereal disease at the time of screening may infect a recipient by acquiring gonorrhoea prior to providing the specimen for insemination.

A relatively new and entirely different field of study relates to the reproductive effects of drugs and disease in the male parent. For instance, in rodents, some narcotics,

including methadone, administered to the male but discontinued prior to mating have been associated with abortion, runting and reduction in number of progeny. Similar effects have been observed with alcohol. In both animal and human studies, diphenylhydantoin has been found in the seminal fluid following administration of this anti-convulsant to the subject. Future studies may reveal whether the drug has any effect on the sperm. Although sperm count and morphology are affected by acute viral diseases in the male, the reproductive significance of these changes has not been established.

As far as we can tell, there are no congenital malformations that could be ascribed specifically to artificial insemination as the percentage of AI babies with known congenital defects is less than is expected after natural conception. However, it is recommended that long-term follow up studies be carried out to provide an improved basis for guidelines in the selection of potential donors for artificial insemination.

Number of donations Theoretically, one donor could be responsible for several hundreds or even thousands of pregnancies when frozen sperm is used. In this event he might inadvertently propagate some unforeseen genetic disease on a large scale, and increase a risk of inadvertent consanguinity which already exists in the community. To obviate this danger restrictions must be put on the use of donated specimens. One practice is to limit the number of specimens from a single donor to perhaps 30, which with a 15% success rate might be followed by 4 to 6 pregnancies. Another approach is simply to limit donors to 6 pregnancies.

2. PRESERVATION AND IMPORTATION OF HUMAN SPERM

Sperm may be preserved by freezing, the semen specimen being maintained at very low temperatures in a sperm "bank". This method is used for donor sperm in at least three clinics in Canada, and there is a growing interest in sperm storage for the preservation of future fertility, i.e. artificial insemination with husband's sperm (AIH). The latter use applies to men who will undergo extensive chemotherapy or radiotherapy for the destruction of a tumor, because such therapy will also destroy spermatogenic functions. Also a number of men when considering vasectomy have expressed a wish to have their sperm frozen, possibly to be used for insemination at a later date.

The need for quality control of sperm-freezing techniques becomes all the more important as there may be storage failures, and the fertilization potential of stored human specimens is unknown.

The Committee was not able to carry out a systematic review of the existence and operations of sperm banks other then those affiliated with a university or another major referral facility. Where the latter does not exist, there is a demand for sperm from commercial services for AID and for commercial sperm storage for the preservation of fertility (AIH).

The Committee was not able to determine the number of human sperm specimens imported privately each year into this country. Members were, however, advised that importation occurs from commercial sperm banks in the United States which advertise their products in certain medical journals.

In the animal breeding business the large number of progeny from any one animal makes the requirement for a permit to import sperm both desirable and practical.* The Committee felt that for human sperm there was no general need for importation and since adequate controls over the commercial banks in other countries was not feasible, importation of human sperm should be prohibited. It was recognized that in the future it might be possible to develop methods to evaluate properly the quality of these products in other countries.

It was the Committee's opinion, after thorough deliberation, that a sperm bank that was not attached to a university or to some other publicly owned agency might be liquidated at any time. It is unlikely that such a sperm bank, whether in this country or another, would be able to provide equal accountability for care in the screening and selection of donors, for the reliability of documentation of important information, and for the quality of the freezing process. Furthermore, if the revenue should become inadequate it could cease operations, with the probable loss of all sperm stored for preservation of fertility.

We therefore recommend that until regulations establishing federal standards of quality are in effect for Canada the importation of sperm from commercial human sperm banks should be prohibited and that no new human sperm bank should be allowed to operate outside the jurisdiction of a university or other publicly owned agency.

* according to country such permits may require testing for absence of disease, absence of hereditary disease in offspring and ancestors, and even testing for carrier state of certain undesirable genes.

The committee was not able in the time available to determine whether or not existing legislation would permit the federal regulation of the acquisition, preservation and importation of sperm. Nevertheless, it believes that the following recommendations included in this chapter should be implemented.

2.0 Federal regulations governing standards for the acquisition, preservation and importation of human sperm should be established.

.1 Standards for donated sperm should ensure in so far as is possible that the semen is not infectious, that the donor does not have a transmissible disease, that the specimen has been collected properly and that storage conditions will not unnecessarily impair the quality of the specimen.

.2 The minimum standard to reduce the risk of genetic disease should be the completion of a detailed genetic inquiry.

.3 Minimum standards for number, motility and morphology of sperm in a specimen to be used for artifical insemination should be established.

.4 Donor selection procedures should ensure that a limit to the number of pregnancies from any one donor may be set.

.5 Until regulations establishing federal standards of quality are in effect for Canada, the importation of sperm from commercial human sperm banks should be prohibited; and no new human sperm bank should be allowed to operate outside the jurisdiction of a university or other publicly owned agency.

In addition it is recommended that long term follow-up studies should be carried out to provide an improved basis for future guidelines in the selection of potential donors for artificial insemination.

CHAPTER III

GUIDELINES FOR CENTRES WHERE ARTIFICIAL INSEMINATION OF DONOR SPERM IS AVAILABLE

The committee has recommended that AID be available only where guidelines are met to safeguard the interests of donor, recipient and progeny. The requirements to be met are described under the headings of:

1) record-keeping
2) counselling the prospective recipient couple
3) consents required for AID
4) procedures for the insemination of donor sperm
5) procedures to be followed if an infant is born with an abnormality.

1. RECORD-KEEPING

Increasing information about genetic illness and congenital defects creates a new responsibility in our society. In the context of artificial insemination of donor sperm this responsibility is in conflict with the desire to keep separate the lives of the donor and of the recipient. In addition, the child's desire to know his or her origin is in conflict with the donor's wish for privacy. There is no question that information acquired during the course of history taking, physical and laboratory examinations should be carefully recorded; the pros and cons of the controversy discussed below relate to how the record system links donor and recipient. It must also be recognized that the keeping of identified records does not guarantee that the ostensible donor is in fact the biological father.

The Case for Keeping Linkable Records (Record Linkage)

The case for record linkage is made on several grounds.

Where an infant is born with a congenital defect or genetic disease attributable to the use of sperm from one donor, the donor can be made aware of the implications of this for him, and not be asked for future donations. Further, the donor can be informed if the recipient acquires an infection traceable to the donation. From the ethical standpoint, it would seem wrong to withhold such information from the donor.

Linkable records can also serve to identify an intended marriage between people of such a close degree of blood relationship that the possibility of genetic defects in their progeny is dangerously enhanced.

Record linkage would also enable AID parents to have redress in the tradition of law against a physician who did not take reasonable steps to inquire about the donor, and against a donor who knowingly or negligently gave false information concerning his genetic background or medical history.

Finally, record keeping would enable an AID child to locate and identify the donor to satisfy his or her search for biological roots. The committee appreciates the importance of this kind of knowledge, including its genetic implications.

Two of these arguments seem not compelling to the committee. As we have said in Chapter 2 the likelihood of consanguineous intermarriage is no greater for AID progeny than in the community at large, provided that reasonable precautions are taken to limit the number of specimens obtained from a single donor. Further, the committee thinks that where there is no genetic defect, the importance of anonymity outweighs the need for information on biological descent.

However, the prevention of genetic disease and the need for possible legal redress seem to demand that links be kept in some form between the records of the donor and those of the recipients.

The case against keeping linkable records

The case against keeping linkable records is also made on several grounds. Firstly, the donor may not be the biological father of the child born after AID.

Secondly, with a few exceptions, there is not in this country, a legally protected right of the confidentiality of medical records. Even in the two provinces which attempt to give by Statute some protection to the privacy of medical records an AID donor may be outside the protection the law gives. Therefore, the donor should be advised that the records held by the physician may generally be subject to scrutiny in the event of legal action, just or frivolous, being initiated.

The law is not clear on the donor's legal relationship to the child fathered by his sperm donation. For instance, it has been suggested by some legal writers that he may be liable for the child's maintenance, and have the same obligations (and rights) as the father of an illegitimate child.

The committee has been advised and accepts that for all practical purposes it may be impossible to obtain donors if they cannot be assured anonymity. (This is particularly so in view of imprecise state of the law).

In light of the legal obligations to produce medical records by Court order, the only way of assuring anonymity would be to not maintain identified records of donors and recipients which can be linked.

In law the physician must exercise a reasonable degree of skill and knowledge in treating his patient. While it is likely this is the standard that the law would require of a physician in the use of AID there has been concern that a higher standard of responsibility might be required. For instance, the physician may be an insurer for any ill results that might be caused by his action even though he could not have prevented these by reasonable care nor have foreseen the actual consequences. It has even been suggested that the doctor may be liable for the support of the child. Doctors at present run the risk of such difficulties having to be resolved by the Court.

Although it recognizes the arguments advanced above, the committee is of the opinion that the benefits of the maintenance of records which can be linked outweigh the disadvantages. It would therefore like to recommend that linkable records be kept in AID. However, at present this recommendation cannot stand until several important legal steps have been taken.

The main impediment to the maintainance of records would be removed by the enactment of provincial legislation that ensured:

1) That no legal relationship exists between the donor and the child fathered by his sperm.

2) That the donor has no legal responsibility to anyone arising from the sperm donation if he has given full and accurate answers, to the best of his knowledge and belief, to the questions asked of him by the physician involved, concerning his genetic background and medical history.

3) That the standard of care required by the physician is that of reasonable care and that the physician has no legal responsibility to the child beyond exercising that reasonable care in the obtaining of sperm and the insemination.

Every effort to ensure donor anonymity should continue to be made. A system should exist and be made known to the donor and to the recipient which will as much as is

possible guarantee the anonymity of the donor's participation as long as the information he gives concerning his genetic and health history is accurate to the best of his knowledge. It should be made clear both to the donor and to the recipient that no information is available to the donor unless the child born from AID is found to have a significant congenital defect or an important genetic disease is diagnosed. In this circumstance information should be limited to the medical facts and not reveal identity.

The anonymity of the donor could be protected by the statutory establishment of a board with the object of inquiring into any legal claim arising from a genetic or congenital defect in an AID child. This board, with the power of a commissioner under the Federal Inquiry Act would have the responsibility of investigating on behalf of the complainant. The board would determine if there was a prima facie case of incorrect information being purposely or negligently given by the donor, or a prima facie case of negligence on the part of the physician in obtaining information from the donor. In the latter situation, while the donor's name would be revealed to the parties it would be protected by law from publication. Such a board should be established by means of a uniform provincial statute which could also deal with other legal issues relating to AID.

Maintenance and custody of records

Inactive medical records are generally preserved for both medical and legal reasons. Provincial acts related to Hospitals and Health Disciplines require that records be retained from five to more than 20 years depending on the type of record and whether it be a physician's private record or a hospital record. Because of the variability and imprecision of provincial Limitation of Action statutes some experts recommend that for protection from civil action, private records should be retained for as long as possible or, for example, at least 10 years from the date of the last entry.

While it has been suggested that a central registry be set up to record all cases of AID compiled from information which the practitioner would be required to submit, the implementation of such a scheme would jeopardize the anonymity of the donor, the recipient and the AID child; it would add to the paperwork of the physician; and it would be expensive. The objectives of such a registry besides providing information for research, are not clear to the committee.

Thus, if linkable records related to AID are to be maintained, then for the protection of all parties, records should be kept long enough that for practical purposes most genetic defects would be manifest in the child. The committee recommends that records should be maintained which collect all relevant and available information on the donor. A separate record should document the history and the physical, laboratory and follow-up data on the couple and progeny.

In the case of frozen sperm, which might be kept for years before use, a particular problem arises.

The Committee is of the view that physicians dealing with the AID process should have the responsibility of maintaining all records in accordance with generally accepted medical practice and any provincial statutes which govern medical and laboratory records.

In addition, the committee believes that the length of time that linkable AID records should be maintained be determined bearing in mind the factors mentioned above, and that the requirement be incorporated in provincial statutes. In all cases, the records of the donor and of the recipient should be kept separately.

Conclusions on record keeping

In concluding this rather complex section of the chapter we wish to summarize the medical reasons for and against record linkage. If the recipient develops an infection, if a congenital abnormality occurs in the child, or later a genetic defect becomes apparent, then linked records are desirable. On the other hand it is not possible to guarantee that pregnancy has resulted from any specific insemination; it is not possible for some centres to have multiple inseminations in the same cycle from the same donor; and some donors are repelled by the possibility that in years to come such a connection may be disclosed or alleged.

The Committee agrees that linkable records should be maintained until most congenital malformations and heritable disorders can be ruled out. However, for practical purposes it may be impossible to obtain donors if they cannot be assured anonymity. Therefore, the committee recommends that provincial legislation be passed to protect the donor from unfounded or frivolous legal action. When protective legislation exists, the committee recommends that links be kept between the records of the donor and those of the recipient.

2. COUNSELLING OF THE PROSPECTIVE RECIPIENT COUPLE

All the issues arising from artificial insemination of donor sperm require discussion in a detailed interview. The couple should relate how they arrived at their decision to consider AID. The counsellor will generally ask direct questions about the husband's feelings and whether adoption has been considered. It has not been customary in Canadian clinics to have a formal psychological evaluation.

The couple are then given general information about the selection of donors, and the collection of specimens. The steps taken to ensure confidentiality for all parties are described and the matching of characteristics of donor and husband available in that particular clinic is discussed. The physical details of artificial insemination are described, and an estimate of costs is given.

At the first interview the results to be expected are discussed with the couple. The couple is informed of the expected pregnancy rate from AID and the average number of visits that may be anticipated. They are assured that the chance of a normal pregnancy has been reported to be the same with artificial insemination as with natural conception.

The legal status of the child born after conception through AID must be discussed, together with the question of whether or not the AID origin should be disclosed to the child. The doctor should ensure that the prospective parents are aware of the physical and psychological importance of knowledge of one's genetic heritage, the current trend of adopted children to seek out their biological parents, the present legal disadvantages of revealing the AID origin, the risk of discovery by accidental disclosure, the possible need at some time for disclosure for the sake of the child, the lack of certainty that the origin is AID and the importance of donor anonymity. The ultimate decision whether or not to advise the child will be in the hands of the parents.

It is essential that counsellors for couples considering AID should be as familiar with the ethical and family considerations (discussed in Chapters V and VI) as they may be with the clinical aspects of the subject. Accordingly the Committee recommends that:

Counselling for couples considering AID should include discussion of a wide range of clinical, ethical, legal and family issues.

3. CONSENT REQUIRED FOR ARTIFICIAL INSEMINATION OF DONOR SPERM

Consent forms should be developed in every centre providing artificial insemination of donor sperm. It is of the utmost importance that informed consent be obtained from the donor and from the recipient couple.

In order to provide informed consent the form for the donor must require that: he agrees to supply full and true information about heritable disease in himself and his relatives, and to undergo a physical examination and the required tests; he agrees not to seek out the identity of the recipient's child or children; he understands that the specimen will be used for the purpose of insemination; that any financial or other compensation he receives is for loss of time, inconvenience and travel expense; and that the outcome of the insemination will remain undisclosed to him unless it is thought that a resultant congenital or hereditary condition in the progeny may be important to his own interests or unless it affects his health directly.

The consent form for the couple must ensure that they understand: the purpose of the procedure, the source and screening of donors the procedures used in the centre; the need for confidentiality for the donor and the recipient couple, the extent and limits of record-keeping, the risk of abnormal offspring, the present situation regarding the legal status of the AID procedure and of the resulting progeny, the cost of the procedures, and the pregnancy rate to be expected. The couple must also agree to accept responsibility to report to the physician or the centre regarding the health of the child born following AID.

The Committee recommends that:

Clinics offering AID should have for the donor and the recipient couple, clearly written consent forms using ordinary language which disclose the risks and responsibilities involved in the procedures which each of them is considering.

4. PROCEDURES FOR THE INSEMINATION OF DONOR SPERM

The details of the procedures followed in Canadian clinics vary, but the principle is always to deposit sperm just before ovulation occurs.

A test of the woman's tubal patency to ensure that the ovarian tubes are functioning normally is necessary and may be done before AID, or it may be delayed and done after a few months if pregnancy does not occur. Women having AID are often required to keep a record of their daily basal temperatures (taken orally immediately after waking up). In each cycle two or three inseminations are done at 48 hour intervals during the days preceding ovulation. The appointments are planned from the temperature and menstrual data of previous cycles.

The insemination technique depends upon the type of specimen that is available. When a complete ejaculate (5 ml.) is used for a single insemination it may be inserted in the vagina using a syringe and plastic tube without a speculum. When the ejaculate must be divided between two recipients a speculum is introduced and the smaller volume is deposited within the cervical canal. The latter technique is also used with frozen semen which is supplied in plastic straws containing about one millilitre of semen. Some clinics supply a cervical cap to prolong sperm contact with the cervix. Whatever the technique used the recipient remains supine for several minutes.

In some clinics the semen specimens are mixed in order to avoid the linking of donors to specific recipients. All the specimens collected on a single day are mixed and a small fraction is removed from the pool for each insemination. This procedure may reduce the motility of sperm as a variety of agglutination reactions may occur, and the subsequent

fertilizing capacity will be reduced. Moreover, the committee is of the opinion that mixing sperm samples is improper because it effectively prevents any search for possible cause when a congenital malformation is discovered, or for the identification of patterns of inheritance when an hereditary disorder is discovered. Pooling also widens the exposure of recipients to multiple donors and thus increases the risk of acquiring a transmissible infection.

Intercourse during courses of artificial insemination has been both advocated and condemned. While from a social and family point of view it is probably more satisfactory to encourage intercourse during the cycle when AID takes place, there is evidence that mixing semen in this way may produce agglutination reactions such as those referred to above, which may inhibit the potential activity of the donor specimen. For this reason, couples are often advised to abstain from intercourse for two days before and after the inseminations.

The Committee recommends that routine pooling or mixing of sperm from different donors for artificial insemination should be avoided.

Use of frozen sperm

While frozen sperm has been used for artificial insemination in the cattle industry for some fifty years, the first successful AI using frozen human sperm was reported by Bunge and Sherman in 1953. Since that time it has been widely used, and significant advances have been made in sperm cryo-preservation techniques. In spite of this the amount of physical and chemical change to the sperm during the freeze-thaw cycle remains uncertain. In France the Centre for the Study and Conservation of Human Sperm (CECOS) has had

extensive experience with operating a frozen sperm bank and with the distribution of the sperm specimens to physicians in many parts of the country. In general the results have been most satisfactory. It is also evident that certain donors make better candidates for this technique than others. Considerable research remains to be done to improve cryo-preservation techniques and to achieve a higher recovery rate. Further details on the freezing, preservation and recovery of sperm after freezing are included in Appendix 3, together with some comments on the results of using frozen sperm.

5. PROCEDURES TO BE FOLLOWED IF AN INFANT IS BORN WITH AN ABNORMALITY

In the event of the birth of a child with one or more congenital malformations or the manifestation of an inherited disorder, it is essential that all reasonable steps be taken to establish a correct diagnosis. The recipient couple should receive genetic counselling about the probable cause(s) for the disorder, and its possible association with AI. The probability of the same condition occurring in a subsequent child should be discussed. If the condition is such that the donor's offspring are at appreciably increased risk, and particularly if prenatal diagnosis is available, consideration should be given to the donor's right to be informed accordingly.

CONCLUDING COMMENTS

In preparing this section the committee has been made aware of the legal risks for the physicians and donors involved with AID. While the committee has recommended that the practice of AID occur only when guidelines safeguard the donor, the recipient and the progeny, it finds that these are

now more effective in safeguarding the progeny and the recipient than the donor or the physician. Indeed, the legal position of the donor and physician is such that in 1977 the Canadian Medical Protective Association repeated their advice to physicians not to practice AID. If some measure of protection is not legislated to make the legal duty of care the same as in other medical procedures, then in an increasingly litigious community, the availability of AID may well greatly diminish as physicians and donors become aware of the unreasonable legal risks to which they are exposing themselves. If this occurs, there may well be increased demand from Canadian infertile couples for AID from unregulated sources.

In view of the present legal risks to donors and physicians, we recommend that the Minister of National Health and Welfare bring the matter to the attention of the Provincial Ministers and encourage them promptly to enact remedial legislation.

The following recommendations sum up this chapter:

3. AID should be available only where guidelines are met to safeguard the donor, recipient and progeny.

.1 Records should be maintained which collect all relevant and available information on the donor. A separate record should document the history and the physical, laboratory and follow-up data on the couple and the progeny.

.2 Provincial legislation should be passed to protect the donor from unfounded or frivolous legal action. When protective legislation

exists, the committee recommends that links be kept between the records of the donor and those of the recipient.

.3 Counselling for couples considering AID should include discussion of a wide range of clinical, ethical, legal and family issues.

.4 Clinics offering AID should have for the donor and the recipient couple, clearly written consent forms using ordinary language which disclose the risks and responsibilities involved in the procedures which each of them is considering.

.5 Routine pooling or mixing of sperm from different donors for artificial insemination should be avoided.

.6 In view of the legal risks to donors and physicians, the Minister of National Health and Welfare should bring this matter to the attention of the Provincial Ministers and encourage them promptly to enact remedial legislation.

CHAPTER IV

AID: AN OVERVIEW OF THE ETHICAL ISSUES

Artificial insemination by donor is not new. Familiarity with this technique of human reproduction may lead some to believe that all the major ethical and social problems raised by this procedure have long since been resolved. This is not the case. There is a need to review the major moral and ethical issues associated with AID; and so we must first identify them.

AID and Basic Human Values

Human reproduction is an eminently social and profoundly interpersonal act. Techniques which modify traditional patterns of reproductive behaviour inevitably introduce changes into the relationships and the institutions designed to regulate and promote that behavior.

A hierachy of human values clusters around these relationships and institutions. These values have emerged slowly and, indeed, not without pain and peril, over long periods of human history. For these reasons techniques that introduce changes into these relationships and permit possible transformations of these values raise questions of a moral and ethical nature.

AID: Moral and Ethical Considerations

Many conditions have to be fulfilled for AID to be morally acceptable in principle. Further conditions have to

be met for AID to be ethically acceptable in fact. Several questions identify these conditions in each case. The questions also formulate the key issues associated with AID as a technique of human reproduction.

The most important of these questions has to do with marriage. The report of the commission set up in 1945 by the Archbishop of Canterbury argued that AID could not be morally accepted because it "violates the exclusive union between husband and wife and involves a breach of the marriage." Pope Pius XII expressed the same position in similar terms in 1949: "Only marriage partners have mutual rights over their bodies for the procreation of new life, and these rights are exclusive, non-transferable and inalienable." AID is to be morally rejected, this statement argues, because it violates the exclusive, non-transferable and inalienable character of these mutual rights.

Do these positions truly reflect what happens to the structure of a marriage relationship when a couple turns to AID to bring a child into their marriage and transform their marriage into a family?

The marriage relationship, in Western Christendom and in many other cultures as well, most definitely involves the kind of exclusivity and totality mentioned in the two positions above. A marriage relationship begins in the mutual promise between a man and woman to live precisely this kind of relationship. Moreover, the promise is meant to be irrevocable, "until death do us part".

We have come to understand that the marriage relationship is not simply or even primarily contractual. The relationship involves and harbors the expectation of more than a bartering exchange of objects. The relationship begins in a promise of body and person which tends by its very logic to give a new and lasting shape to the marriage partner's whole life. A relationship which begins with a gift and gratitude and survives as a promise which reshapes one's whole life is a covenant relationship.

Covenant relationships are of several kinds. Marriage is a unique kind of covenant relationship precisely because of the exclusivity and totality of its sexual promise. Totality, because the sexual promise of marriage encompasses many levels of communication. The sexual language is rich and complex. In marriage, that language is a promise of genetic communication to bring about new human life. But trust, belief, hope in the marriage partner, the union of one's quest for personal identity and fulfillment with the like quest of one's spouse, and unbounded and unconditional acceptance of one's loved spouse and a like gift of oneself - these are all moments of the sexually embodied communication which constitute the marriage relationship. Genetic communication is meant to be an expression of, and one moment of this more comprehensive sexual communication and promise of one's person. The marriage relationship calls for expression across the full register of the sexual expression of one's being. The exclusivity of the marriage relationship means that this full sexual communication of one's person is reserved for one's spouse.

We generally hold adultery to be such a profound violation of the marriage promise and of its sexual exclusivity and totality as to signify a death or destruction of that relationship. But AID, as such, is not adultery. It does not involve sexual intercourse between the wife and donor. For that reason it does not involve the sexual communication between wife and donor at all of those levels which constitute the marriage relationship. Genetic communication between wife and donor takes place via AID, but that genetic communication does not employ the sexual language.

This analysis really calls for further development. However, enough has been said to question meaningfully whether AID is in principle such a serious violation of the marriage promise and the structure of the marriage relationship as to signify a destruction of that relationship. AID does not demand or mean that husband and wife transfer and alienate their mutual rights over one another's body for the procreation of new life. The donor is not being given a right over the wife's body, much less over her person and her sexual communication of love and person to her husband. She reserves this, by assumption, precisely for her husband.

AID procreation of a child does interfere with the exclusivity and totality of the marriage relationship on the level of genetic communication. But it is difficult to say that this intervention from a third party, willed and mutually accepted by the couple after prolonged and open discussion, constitutes a structural betrayal of the marriage promise.

It should be emphasized that our assumption here is that the marriage partners turn to AID after they have already made a marriage promise which included the expectation of a child and of becoming a family. The decision of AID procreation may be seen, in the face of the husband's irreparable sterility and in the absence of a possibility of adoption, as the expression of these partners' taking up their marriage promise again and renewing it to one another. The donor's genetic communication may be taken up into this renewed promise and then carried to full familihood by the couple's continued exclusive and personally total sexual communication of themselves to one another.

Because this is in principle possible, AID should not be morally rejected in principle as involving a violation of the exclusivity and totality characteristic of the structure of the marriage relationship.

AID procreation of a child does involve an exception, a profound and weighty exception, to the normal structure of a marriage relationship. Indeed, procreation of the child to come is not achieved via the husband's genetic communication with his wife. On the other hand, it is no less true that the donor does not, by reason of his communication of genetic material to this marriage, obtain rights over the body, much less over the person of the wife. AID procreation presents society with an exceptional form of marriage relationship. True, but the claim that such a marriage is not, despite the couple's "good intentions", really a marriage is gratuitous and unjustifiable. Too much personal and bodily exclusivity and totality can be retained in such a marriage to demand its moral rejection in principle as a violation of the fundamental structure of the marriage relationship.

Of course many other questions remain. The moral acceptability of AID in principle does not mean that AID is morally acceptable under any condition. The following list of questions direct attention to some of the principal conditions which have to be considered in elaborating the ethics of AID.

1. Should AID be considered only as a reproductive procedure of last resort? More concretely, is it responsible to contemplate AID when adoption is possible? Should AID be considered to be a morally viable option only when adoption is not possible because of the non-availability of adoptable children?

2. Should AID be considered only when it is a question of a married couple as the receiver of AID? Is a common-law marriage a sufficient guarantee of stability for the couple and for the family environment of the future child? Is AID to be considered a responsible choice in the case of a single woman of avowed homosexual inclination?

3. Would the exerting of pressure of one partner on the other be sufficient to make AID an irresponsible and unwise decision for this couple? What degree of psychological balance and maturity should be required of both partners? How is this to be ascertained? Who is the judge? According to what criteria?

4. Should the donor be a single man or a married man? A married man who has already had children? Is the consent of the donor's wife essential? Is anonymity essential? Without exception?

5. There is general agreement that donors should not be haphazardly accepted. They should be submitted to testing to assure the quality of the sperm. How sophisticated should these tests be?

6. Should donors be paid for the offer of their sperm? Does payment introduce an unacceptable commercial dimension to an activity which should remain in the domain of interpersonal gift and gratitude. Is there a likelihood that the payment of donors will lead to an unacceptable number of unsuitable contributors?

7. What arrangements are necessary to assure that the donor of sperm is acting with a maximum degree of responsibility with respect to the child who will be born from his genetic contribution? One of the traditional objections to AID, it will be recalled, is that the donor abandons all responsibility in an area of human activity which demands a maximum of responsibility.

8. The claim has been made that the necessary secrecy involved in AID obliges the medical practitioner, the husband and the wife, and the donor or donor couple to conspire together to deceive the child and society as to the child's true parentage and genetic identity. The claim here is that AID necessarily involves a violation of truth, as in the case of cover-up when a child is conceived via extra-marital intercourse. AID would involve a similar violation of truth which is willed and accepted in advance. This situation raises several questions.

Should the "secret" be kept from the child? For how long?

Should the secret be kept from the recipient couple's broader family? Realistically, can such a secret be generally kept? If not, is there not a risk that the child will find out accidentally?

If the child is to be registered as the legitimate child of the receptor couple, is it wise to keep no records of the child's genetic origin?

If records were to be kept, primarily for medical reasons, can anonymity be assured?

9. Complaints have been expressed on the lack of adequate and systematic follow-up studies of AID. Should AID couples and their children be submitted to the potential disturbance that could be caused by such studies? On the other hand, can we hope for an adequate regulation of AID without the data obtainable by such studies?

10. Does the cryobanking of human sperm favor the logic which would increasingly separate the reproduction of human beings from the context of interpersonal love, from the context of promise, fidelity, and gratitude? Does the cryobanking of human sperm represent one step, via new developments in reproductive technologies, towards a literal production of human beings, with eugenic motivation?

This listing of questions has focussed attention on some of the conditions which have been discussed by the Committee and which have to be considered in order to work out a proper ethics of AID. The listing is not exhaustive.

CHAPTER V

THE EFFECTS OF AID ON THE FAMILY

Introduction

In our society the family is the unit in which children are usually reared. However, some couples are infertile. AID offers a road to parenthood while emphasizing the importance of the family. Since the social father accepts his role from the onset of pregnancy, the child is born in accord with the wishes and actions of both parents. An immediate and long-term potential for good, and harm, is present. It is, therefore, highly appropriate to attempt to study the effects of a procedure such as AID on the family.

Existing Attempts to Measure the Effects of AID on the Family

In the past various authors (often psycho-analytically oriented) voiced speculative concerns about problems that might occur in AID created families. There were in addition demands for objective studies revealing the actual outcome of AID. In the last decade, there has been less psychiatric speculation. Attempts to measure objectively the outcome of AID in families has resulted in a realization by social scientists and clinicians that the traditional secrecy permeating AID effectively precludes collection of objective data. Many existing ways of measuring social phenomena are relatively "soft", lacking accepted scientific validity.

How can the effect of AID on a family be measured? We have no "marital stability index" to apply to families and no objective techniques for assessing "successful parents" or

"happy children". The literature consists in general of reports by physicians of their clinical experience. Their results are generally positive. Questionnaire surveys of the family sometime after the baby arrives have also reported favourably on AID. They too are the product of the physician protagonist and are administered to a survey population who had initially made a strong personal commitment to the procedure.

Objective studies of the physical and emotional health and intelligence of the children conceived by AID are possible. Although tools exist to measure these factors, the confidentiality that surrounds AID precludes at present studies of this nature.

The fact that couples with a child conceived by AID frequently seek to have additional children by this method is reassuring to its proponents. The indications are that AID is a procedure with positive results, but in truth, no one really knows. This situation seems unlikely to change in the foreseeable future.

The couple seeking a child through AID are seeking personal growth through family growth. There is explicit acceptance of their joint infertility and of joint responsibility for any children conceived through AID perhaps even more responsibility than is felt by many couples conceiving "normally". The development of positive intramarital feelings is thus facilitated, e.g. "I married her not only to be my wife, but also to be the mother of my children" and "how he must love me to let me have our baby this way". There is the additional satisfaction for the woman of carrying and giving birth to her own baby.

There may be concerns about possible "psychological traps": a mother may develop obsessive fantasies about the donor, she may later reject her husband by excessive attachment to "her" child, the father may reject the child as not being his own; the child may have difficulty establishing his/her personal "identity" because the social father is not the biological father. Therefore, the child may be more vulnerable at times of later family stress. Separation of sexual love from procreation may lead to depersonalization of the marriage bond, although in practice no evidence has been established to suggest these problems occur to any significant degree.

Earlier in this report (Chapter III) we have mentioned concerns related to unwitting subsequent consanguinous marriage and the development of unwarranted anxiety that would arise in a child if his or her social father subsequently developed an inheritable disease.

For society the practice of AID involves risks as well as benefits. Overall sex ratios might in the future be manipulated by sex selection through treatment of sperm before insemination. More gravely the potential for gene selection might interfere with our present patterns of procreation based on mutual attraction. However, we should not regard all potential for selection as ipso facto undesirable. For instance a couple might resort to AID when the presence of severe genetic disease reduces the chances of normal progeny.

Concluding Comments

The impression gained by the committee is that AID rarely harms and may often strengthen the family. While the difficulties of conducting long-term studies appear insurmountable we believe that such studies are needed so that the practice of AID may be carried out with a better understanding of both the benefit and the risks. The family implications require that such studies should concern not only the recipient family but the donor family.

CHAPTER VI

CONCLUSION

This report, in response to the Minister's assignment, presents a number of recommendations and defines some unresolved issues on the storage and utilization of human sperm. It also examines questions that are inseparable from the assigned topics, as these questions arise whenever AID is discussed.

Much remains to be done: from the research point of view there has been no concerted attempt to reduce the prevalence of male infertility. One obvious step would be to encourage more epidemiological studies on male infertility. For example to what extent does exposure to industrial by-products lead to a gradual decrease in the sperm counts of young male workers. Prevention of infertility is preferable to the use of sperm banks, AID and other treatments for male infertility. Although the Committee has recommended in this report long-term follow-up studies of families after AID, there remains a growing need in the field of male infertility for research that may reduce the demand for AID.

Many questions remain unanswered. There is virtually no information on the variety of emotions and attitudes that must occur among young men who become sperm donors. Is the donor fearful of disclosure of his identity? Is it correct to assume that donors are generally motivated by unselfish desire to help the infertile couples? Donors and the

recipient family require competent counselling and the education of both would be assisted by more information about the process. This together with clinical data could be included in a pamphlet on AID for donors and recipients.

Another question briefly discussed by the committee was the use of AID for the fertilization of a woman without a male partner. The committee was not able in the time available to discuss the subject in sufficient depth to form recommendations.

There are many other questions related to artificial insemination that require study. In general, the very privacy of artificial insemination will preclude, in our culture, the recruitment of AID progeny in numbers sufficient to establish the effects of artificial insemination. As optimal studies may thus be impossible, the committee hopes that this report will stimulate public awareness and a level of discussion that will result in the best quality of outcome within the law. To ensure the quality of life for thousands of AID children who have been or will be born in Canada the Committee urges the widest possible distribution of this report. Thus it is our hope that the Minister of National Health and Welfare will see fit to provide for the publication of this report for widespread study. For some of the public, it would be timely and useful to know about the state of the art. Many will be reassured that the considerations of those involved in artificial insemination are not confined to science and technology but extend to the humanitarian aspects of procreation.

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4. SPERM BANKS
5. APPLICATION OF AID TO INFERTILITY PROGRAMS
6. GENETICS
7. REVIEWS OF RESULTS
8. PROGENY
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APPENDIX I

ADVISORY COMMITTEE ON THE STORAGE AND UTILIZATION OF HUMAN SPERM

PROPOSED TERMS OF REFERENCE

The Committee will advise the Minister of National Health and Welfare in relation to the storage and utilization of human sperm, having considered:

1) the extent of storage and utilization, actual and projected, of human sperm in Canada;
2) methods for collection, preservation and reconstitution of human sperm;
3) methods of assessment of donors and recipients, the counselling of prospective parents and the effects on the child and the family;
4) the need for the control of the importation of human sperm from other countries;
5) the biological, legal, medical, philosophical, religious and social implications of the use of stored human sperm;
6) the scientific evidence concerning the effect of storage on the genetic integrity of human sperm, the course of the resulting pregnancies, and the health of the resulting offspring.

APPENDIX II

ARTIFICIAL INSEMINATION OF DONOR SPERM
IN CANADIAN CENTRES, 1979

Centres	Year Started	Current Workload (Latest six months)		Estimated Pregnancy Rate	Known Congenital Defects	Known Pregnancies (total)
		New Referrals	Number of Inseminations			
1	1968	100	800	65	3	800
2	1973	52	120	60		29
3	1978	20	75	60		12
4	1968	44	379	60	3	152
5	1977	22	63	63	1	34
6	1976	25	20	70		15
7	1971	52	343	72		300
8	1970	16	206	73		32
9	1969	124	448	43	1	92
10	1974	47	300	48		27
11	1970	14	107	36		26
TOTALS		516	2,861		8	1,519
MONTHLY VOLUME		86	476			

APPENDIX III

Freezing Techniques for Human Semen

Early cryo-protective media consisted of a 10% glycerol suspension with specimens frozen in glass ampules and suspended in an atmosphere of dry ice vapour. Sherman introduced the use of liquid nitrogen at -196.5° Centigrade and pioneered work on the concept of time-temperature freezing curves used to preserve as well as thaw specimens. Subsequently, an egg-yolk/glycerol citrate solution has been utilized as a protective medium which appears to give somewhat improved survival in the freeze thaw cycle. Specimens are now frozen in plastic straws, lowering the temperature through a vapour phase followed by immersion in the liquid nitrogen. The optimum warming rate appears to be simply to leave the straws in a room temperature over a period of 30 minutes.

The freeze-thaw cycle involves a number of changes in the sperm. It has been claimed that freezing causes the formation of ice crystals, and that there is a subsequent supersaturation of the fluids and mechanical damage to membranes and other cellular structures. The increased osmolar concentration is thought to result in damage to cellular membranes as well and also to molecular structures. During the thaw cycle, the same mechanical and chemical processes are reversed with subsequent damage. It appears that glycerol protects against the high salt concentration whereas egg-yolk protects against some change in cell membranes.

Specimens from healthy volunteers have been studied by electron microscopy after a freeze-thaw cycle. They showed a disruption and an irregular pattern in the membrane of the acrosomal region. There was swelling of the anterior segment of the acrosome, and thinning of the acrosomal material. The appearance suggested mechanical disruption. Changes were also noted in the matrix of the sperm in the mid-piece of the sperm axis.

The fewest changes occurred after the pre-treatment of the semen sample with 10% glycerol as the cryo-protective agent. In spite of a variety of cryo-protective techniques and freeze-thaw cycles, a loss of sperm motility ranging from 30-50% is reported in a large number of studies.

Specimens with sperm counts between 40-120 million/cu ml and motility between 60-80% are more suitable for long-term storage. The freeze-thaw cycle seems to be the principle cause of the degradation of motility (rather than the length of storage). In the first 36 months following freezing there is no demonstrable loss of motility with time. After 36 months there is a slight progressive decline in the motility, although fertilization has been successful using sperm that had been stored as long as ten years.

Results with Frozen Semen Artificial Insemination

Approximately 1,500 AID pregnancies using frozen human sperm have been reported. In one report on 621 pregnancies there were six congenital anomalies, 50 abortions (8%) and 571 births. These rates were at or below those observed in the obstetrical unit. Another report shows that body height and weight and development, as well as I.Q. levels, in

children born from frozen specimens are at least as high as the average. In most cases, higher than average I.Q. rates were noted. A conception rate of 73% with the use of fresh specimens in 48 attempts resulting in 35 pregnancies was compared with a rate of 61% with the use of frozen semen in 59 attempts for 36 pregnancies in the same clinic. It should be noted that the number of attempts per conception was considerably higher in the frozen group. With the use of fresh donor semen, another clinic found a 70-75% success rate within three to four months, and 90% of the conceptions occurred within the first six months. However, very few adequately controlled studies compared the pregnancy rate and the long term results of the two techniques under similar conditions. There is a demonstrated 30-40% loss of motility after freezing, thus the pregnancy rates vary between 40-60% using frozen specimens.

In Chapter two we discussed limits to the number of sperm donations from a single individual. When frozen specimens are used, 4-6 plastic straws can be prepared from each specimen. Thus 6-8 ejaculations may give use to about 35 useful specimens and 5-6 potential pregnancies, given the slightly lower success rate of frozen specimens.